



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,593	06/27/2001	F. Mark Ferguson	SHP025.1	4461

7590 11/21/2005

Mark S. Leonardo, Esq.
Brown Rudnick Berlack Israels LLP
One Financial Center
Boston, MA 02111

EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/892,593	Applicant(s) FERGUSON ET AL.	
	Examiner Catherine S. Williams	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,11,14-20,23,25,27-31,60,62-65 and 69-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9,11,14-20,23,25,27-31,60,62-65 and 69-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of the claims is withdrawn in view of the newly discovered reference(s) below. Rejections based on the newly cited reference(s) follow.

Claim Objections

Claim 69 is objected to because of the following informalities: line 4 recites “a lock disposed therebetween, for engaging the interior cavity of the collar of the needle hub means” and line 8 recites “the lock captures a portion of the needle disposed proximal to the distal end of the needle in a configuration to prevent displacement of the shield means”. It is suggested that two locks should be recited to perform these two functions instead of just one lock. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kao et al (USPN 6,171,284). Kao discloses a monolithic needle hub (4), a collar (3) with an interior cavity and an extensible and retractable shield (11,12,13) including a plurality of living hinged segments (12). The proximal end of the shield (13) is received in the interior cavity of the collar.

Art Unit: 3763

The interior cavity has tabs (32) and the proximal end of the shield has notches (132). The inside surface of the collar and the exterior surface of the proximal end (13) of the shield engage the limit rotation of the shield relative to the hub. See 3:10-19. The distal end of the shield (11) encloses at least a portion of the distal end of the open ended needle. See figure 4. The exterior of the needle hub is considered a guide surface. The segments of the shield include relief portions adjacent the living hinges that flex inwardly.

Kao meets the claim limitations but fails to include the notches in the cavity and the tabs on the proximal end of the shield.

At the time of the invention, it would have been obvious by one skilled in the art to rearrange the notches into the interior cavity of the collar and position the tabs on the exterior of the proximal end of the shield. Applicant has not disclosed that having the notches inside the cavity and the tabs on the proximal end of the shield versus the opposite provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Kao's arrangement of the notches and tabs and Applicant's invention, to perform equally well with either the arrangement of the notches and tabs taught by Kao or the claimed arrangement. Either arrangement would perform the same function of connecting the needle shield to the needle hub equally well considering both arrangements would securely attach the shield to the hub.

Claims 5-9,11,14-18,20,25,27-29,63,65,69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kao et al in view of Haber et al (USPN 4,950,250). Kao meets the claim limitations as described above but fails to include a lock on the shield between the

Art Unit: 3763

proximal and distal ends which captures a portion of the needle disposed proximal to the distal end of the needle and a retention catch.

Haber teaches a needle shield that includes a lock (16) that engages a notch (18) for retaining the shield in the extended position and a notch/retention catch (20) for retaining the shield in the retracted position. The needle shield also has a plurality of segments (6-1,6-2).

At the time of the invention, it would have been obvious to incorporate the lock (16) and notch (18) into the segments (12) of the shield of Kao. Both devices are analogous in the art of segmented needle shields; therefore, a combination is proper. Additionally, one skilled in the art would recognize that the lock and notch of Haber enhances lateral containment of the needle within the shield after use. Furthermore, one skilled in the art would recognize that the shield of Kao does not provide for a lateral containment of the needle within the shield, i.e. the needle could translate from between the segmented (12) portion of the needle shield. Therefore, one skilled in the art would be motivated to incorporate the lock and notch of Haber into the invention of Kao in order to enhance locking the needle to the shield to prevent needle sticks post use.

At the time of the invention, it would have been obvious to incorporate the notch (20) of Haber into the segmented portion (12) of Kao. Both devices are analogous in the art of segmented needle shields; therefore, a combination is proper. Additionally, one skilled in the art would recognize that the notch of Haber enhances releasable retention of the shield in the retracted position. Additionally, one would recognize that the retracted retention mechanism is Kao (112 and 31) are dependent on rotation of the device and if the collar (3) is accidentally rotated during use the shield could spring forward resulting in injury to the patient and premature

Art Unit: 3763

withdrawal of the needle. The motivation for substituting the lock (16) and notch (20) for the retention mechanism of Kao (112 and 31) would have been to provide a mechanism that would further prevent the needle shield from premature extension and possible harm to the patient.

Claims 1,5-18,20,23,27-31,60,62-63,65,69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber or Thorne (USPN 5,951,525) in view of Kao.

Haber discloses a needle shield that includes a needle hub (12) and an extensible and retractable shield including a plurality of living hinged segments (6-1,6-2). A lock (16) engages a notch (18) for retaining the shield in the extended position and a notch/retention catch (20) for retaining the shield in the retracted position. The shield also includes articulated actuators (14).

Thorne discloses a needle shield that includes a needle hub (90) and an extensible and retractable shield including a plurality of living hinged segments. A lock (126) engages another lock (146) for retaining the shield in the extended position. The shield also includes articulated actuators (118,138).

Haber and Thorne each meet the claim limitations as described above but both individually fail to include a collar on the needle hub with an interlocking engagement that includes notches and tabs. Kao teaches such a collar with interlocking tabs and notches.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to substitute tabs on the shield and notches inside a collar on the needle hub into the invention of either Haber or Thorne. Applicant has not disclosed that having a collar with notches and the shield having tabs as the connection mechanism between the shield and the needle hub provides an advantage, is used for a particular purpose or solves a stated problem.

Art Unit: 3763

One of ordinary skill in the art, furthermore, would have expected Haber or Thorne's connection of the shield to the needle hub and Applicant's invention, to perform equally well. Either connection would perform the same function of attaching the needle shield to the needle hub equally well considering both arrangements would securely attach the shield to the hub.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kao et al in view of Haber or Haber or Thorne in view of Kao. Each rejection meets the claim limitations as described above but fails to include the needle hub having a luer fitting configured to attach to a syringe.

At the time of the invention, it would have been obvious to incorporate a luer fitting onto either of the rejections above. Luer fittings are well known in the syringe art for attaching the needle assembly to a syringe. One skilled in the art would have incorporated a luer fitting onto the hub in order to use a known attachment mechanism.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kao et al in view of Haber or Haber or Thorne in view of Kao. Each rejection meets the claim limitations as described above but fails to include the needle being a double walled needle.

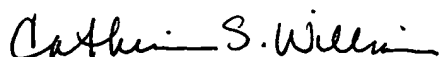
At the time of the invention, it would have been an obvious design choice by one skilled in the art to substitute the needles in the above rejections with a double walled needle. Applicant has not disclosed that a double walled needle provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected needles in the above rejection and Applicant's invention, to perform equally well.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams
November 15, 2005